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INTELLECTUAL PROPERTY GROUP

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EXAMINER

CHEN, CATHERYNE

ART UNIT

PAPER NUMBER

1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/566,338

Applicant(s)

GUDDADARANGAVVNAHALY ET AL.

Examiner

CATHERINE CHEN

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendments filed on Jan. 16, 2009 has been received and entered.

Currently, Claims 1-4, 9-18 are pending. Claims 1-4, 15-18 are examined on the merits. Claims 5-8 are canceled.

Election/Restrictions

Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Aug. 6, 2008.

Applicant's election with traverse of Group I (Claims 1-4, 15-18), the species *Bacillus cereus*, in the reply filed on Aug. 6, 2008 is acknowledged.

Claim Objections

Claims 16, 18 are objected to because of the following informalities:

In Claim 16, a space is required between "wt%."

In Claim 18, part c, a space is required between "upto."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In Claims 1-4, 15-18, the term "ripe" fruit is new matter because it is unsupported by the Specification. Only fruit is found in the Specification.

In Claim 1, the range "about 4% to about 6%" is new matter because it is unsupported by the Specification. Only 4-6% is found in the Specification.

In Claim 16, the term "up to about 10 wt % hexane" is new matter because it is unsupported by the Specification. Only extract without the amount of hexane is found in the Specification.

In Claim 18, the ranges "about 55 degree Celsius to about 60 degree Celsius" and "about 6 to about 8 hours" are new matter because it is unsupported by the Specification. Only 55 degree Celsius to 60 degree Celsius and 6 to about 8 hours are found in the Specification.

New matter must be removed from the claims.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 15-18 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaprakasha et al. (1997, Flavour and Fragrance Journal, 12, 331-333) as evidenced by Tuninst

(<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>) and Li (1996, Malawai: Country Report to the FAO International Technical Conference on Plant Genetic Resource, Leipzig) providing evidence of inherent characteristics of Jayaprakasha et al.

Jayaprakasha et al. teaches fruits of *Cinnamomum zeylanicum* are a dark purple, one-seeded, ellipsoidal berry (Experimental, Plant Material). The specimen was coarsely powdered and subject to hydrodistillation for 4 hours to yield volatile oil, which is dried and stored (see Experimental, Isolation of Volatile Components). Hydrodistillation uses water as solvent. The fruits of *Cinnamomum zeylanicum* are ripe because the fruits are blackish green, purple, pale brown when ripe (see Tuninst, page

10, Plant identification characters). The drying process inherently means the extract is dried, where the moisture content is between 5-6% (see Li, page 18, 3.3 Storage Facilities). The claims are directed to a composition, the composition would intrinsically have antibacterial activity against *Bacillus cereus* in the range of 200-500 ppm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaprakasha et al. (1997, *Flavour and Fragrance Journal*, 12, 331-333) as evidenced by Tuninst

(<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>) and Li (1996, Malawai: Country Report to the FAO International Technical

Conference on Plant Genetic Resource, Leipzig) providing evidence of inherent characteristics of Jayaprakasha et al. in view of Agnihotri et al. (1996, Indian J. Experimental Biology, 34, 712-715).

The teachings of Jayaprakasha et al. with Tuninst and Li are set forth above and applied as before.

The combination of Jayaprakasha et al. with Tuninst and Li do not specifically teach hexane as solvent, its concentration, temperature range, hours.

Agnihotri et al. teaches cinnamomum zeylanium extracted with hexane and tested for antibacterial properties using gram positive and gram negative bacteria (Abstract). Cinnamomum zeylanium was dried and powdered and mixed with hexane and kept on a rotary shaker for 48 hrs to obtain hexane extract, which was filtered and stored at 10 degree (page 712, right column, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hexane to extract compounds from Cinnamomum zeylanicum ripe fruit because cinnamomum zeylanium extracted with hexane has antibacterial properties. One would have been motivated to extract compounds from Cinnamomum zeylanicum ripe fruit with hexane for the expected benefit of extracting compounds with antibacterial properties using gram positive and gram negative bacteria as taught by Agnihotri et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP §

2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability for feeding infants, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655